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Levent Oner

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K.F. ROSS P.C.

5683 RIVERDALE AVENUE

SUITE 203 BOX 900

BRONX, NY 10471-0900

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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EMAIL@KFRPC.COM

ereyes@kfrpc.com

Continuation of 11: In the response file 12/9/2009 Applicant argues that the primary reference USLU et al. teaches 'granules' and not 'microparticles' as recited in the claims (response, pages 3 – 4). The Examiner Acknowledges the receipt of documents provided by Applicant with the response filed 12/9/2009 (Wikipedia-Microparticles and Free Dictionary On Line) in which 'definitions' of diameters of microparticles and granules are cited. Applicant argues that the diameters for microparticles and granules disclosed by said documents provides evidence that the instantly claimed 'microparticles' are outside the scope of 'granules' taught by the USLU reference. Applicant contends that they need no special definition or particle size range to distinguish over the prior art reference of USLU presumably because said particle size ranges disclosed in the Wikipedia and Free On Line documents are commonly known by those of ordinary skill in the art.

In response, the Examiner has already noted in the Final Office Action mailed 9/11/2009 that the instant specification fails to define microparticles and that no particle size range is disclosed (Office Action, page 4). The Examiner also notes that the definition of 'granules' provided by Applicant (vide supra) is directed to the field of geology and not pharmaceutical preparations as described in the claimed invention and the cited references. Further, the definition of 'microparticles' provided by the website 'Wikipedia' has uncertain reliability since the information contained therein may be modified as dictated by the personal preferences of the 'user'. In addition, said website was most recently modified 8/27/2009 and the nature of the modification is unclear. Accordingly, the definition may have been modified and would not be representative of the state of

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the art at the time the invention was filed. Finally, the Examiner, cites US patent 4,900,558 (Barry *et al.*) drawn to granular compositions of ibuprofen in which granules of 0.5 mm are disclosed. This size range overlaps with Applicant-provided definition from the Wikipedia website of microparticle diameter. Accordingly, Applicant is not persuasive in arguing that the granules of USLU fall outside the scope of Applicant-provided definition of microparticles.

Applicant argues that the Watanabe reference does not disclose microparticles (response, page 4). This is found to be not persuasive as the rejection is based on USLU in combination with Watanabe and, as noted above, the prior art teachings (Barry *et al.*) disclose granules that overlap in size with Applicant provided definition of microparticles (*vide supra*).

Applicant argues that Watanabe fails to disclose coating the particles with Eudragit E100 for the purpose of preventing esophageal irritation (response, page 4 – 5). In response, the Examiner has pointed out that Watanabe teaches coating the microparticles in order to improve taste masking and, specifically for bisphosphonates such as alendronate, to improve solubility and absorption (Office Action, page 4). In response to applicant's argument that Watanabe does not teach the same use for a Eudragit coating as Applicant, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the

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basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant argues that Tritthart does not teach microcrystalline cellulose as a diluent and colloidal silica as a lubricant (page 5, response). In response is noted that USLU, the primary reference, teaches these elements and that this represents an argument against a reference individually and one cannot show nonobviousness by attacking references individually (Tritthart) where the rejections are based on a combination of references (USLU in view of Watanbe and Black as evidenced by Tritthart). See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Finally, Applicant argues that neither the USLU, Tritthart or Black references teach coating the microparticles with Eudragit (as taught by Watanbe). Again, this represents an argument against a reference individually and one cannot show nonobviousness by attacking references individually (USLU, Black or Tritthart) where the rejections are based on a combination of references (USLU in view of Watanbe and Black as evidenced by Tritthart). See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).